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Original Article

Drug-coated balloon in patients with in-stent restenosis: A prospective observational study

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ABSTRACT

Aim: The aim of this study was to compare the safety and efficacy of paclitaxel-coated balloons (PCB) and sirolimus-coated balloons (SCB) in patients with in-stent restenosis (ISR).
Methods: This prospective, observational, single-centre pilot study enrolled 85 patients diagnosed with drug-eluting stent ISR. For all the eligible patients, various clinical baseline characteristics were collected, and angiography was performed to evaluate the lesion characteristics. After assessment, patients were treated with either PCB or SCB based on our center's time-based approach. Intravascular ultrasound (IVUS) imagining was used to assess the pre- and post-procedural minimal stent area (MSA). All the patients were followed up and major adverse cardiovascular events were documented for patients in both the groups.
Results: Of total 85 patients with ISR, 32 underwent treatment with PCB and 53 with SCB. A significant difference was noted in the post procedural MSA in both the groups ($p = 0.005$) and the values were 7.01 ± 1.11 mm^2 and 8.01 ± 1.70 mm^2 for PCB and SCB group, respectively. At median follow-up of 3.8 years, no cardiac death was noted in PCB group and one death was reported in SCB group ($p = 0.459$). In PCB group, target lesion revascularization (TLR) was noted in one (12.5 %) patient, while in SCB group TLR was noted in four (16.5 %) patients ($p = 0.920$).
Conclusion: Both PCB and SCB are found to be effective and safe in treating in patients with drug-eluting stents-ISR. Also, the use of DCB with imaging techniques like IVUS enhances treatment outcomes and optimizes patient care in ISR treatment.

1. Introduction

The improvement of interventional therapies has proven to reduce the death rates; however, in-stent restenosis (ISR) in the culprit coronary artery and its associated complications still possess a major challenge.[1] The development of drug-eluting stents (DES) has modified the healing process post stenting, attenuating neointimal formation, led to reduction of ISR rates ranging from 5 % to 10 %.[2] However, recurrence of major adverse cardiovascular events (MACEs), including angina pectoris, acute myocardial infarction, and even sudden cardiac death are few complications associated with ISR.[3]

Over the past decades, various percutaneous coronary intervention (PCI) strategies have been used to treat ISR as the primary effective management, and current European Society of Cardiology (ESC) guidelines stated use of either DES or drug-coated balloons (DCB) as Class IA recommendation for the management of patients with bare metal or DES-ISR.[4,5]

Several studies suggest use of DCB as an emerging alternative in the management coronary ISR and this approach eliminates the need for repeat stenting after ISR, which can expose patients to more metal burden, high costs and to the risks associated with long-term dual antiplatelet therapy (DAPT).[6–8] The routine use of intravascular imaging has IIa/C recommendation in ESC guidelines for detecting the causes of stent failure and also for providing individualized therapy.[9]

The two widely available antiproliferative drugs that could be used as coatings on DCB are paclitaxel and sirolimus. Both of these drugs

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reduce cell proliferation and cell migration.[10] In 2019, Ali RM et al made the first direct comparison between these two i.e., paclitaxel-coated balloons (PCB) and sirolimus-coated balloon (SCB) in treating ISR.[11] Nonetheless, there exists a dearth of scientific literature comparing PCB and SCB, particularly in the Indian context. Therefore, the present study was designed to compare the safety and effectiveness of PCB and SCB in the treatment of patients with DES-ISR.

2. Methods

2.1. Study design and patient population

This was a prospective, observational, single-centre study which was conducted at a tertiary care centre in India from December 2018 and May 2022. The study was performed according to the Declaration of Helsinki and Good clinical Practice. The study protocol was approved by institutional ethical committee and all patients provided written informed consent.

After assessment, patients were treated with either PCB or SCB based on our center's time-based approach. One type of DEB was used for all consecutive ISR patients during a predefined period, followed by the other DEB in the next period, with this cycle repeating throughout the study. Patients with evidence of ischemia induced by DES-ISR, with no more than two lesions in a stented coronary artery with DES, along with a vessel diameter up to 2.5–4.0 mm and a lesion length of no more than 34 mm were considered for enrolment. Major exclusion criteria were acute myocardial infarction within one week before the indexed procedure, more than two lesions to be treated in each coronary artery and more than three lesions to be treated including the non-target lesions. Cardiac catheterization and interventions procedure were carried out according to routine hospital practice.

2.2. Procedure and endpoint

Baseline clinical data including age, gender, presence of any co-morbidities were obtained. Data on the number of lesions and the target lesion artery were obtained on performing angiography. A total of 85 patients diagnosed with drug-eluting stent ISR were enrolled and were randomly assigned to undergo balloon angioplasty of the target lesion with either a PCB ($n = 32$ with Agent paclitaxel-coated balloon, Boston Scientific) or SCB ($n = 53$ with MagicTouch sirolimus-coated balloon, Concept Medical). After clinical and angiographic assessment and randomly selection for PCB or SCB, the lesions were pre-dilated using a smaller balloon and IVUS was performed to record pre-dilatation stent area (minimum). Later, the lesions were properly dilated using a 1:1 scoring balloon and then again IVUS was done to record post-dilatation stent area. Following that, a properly sized DCB (PCB or SCB as allotted) was used and kept inflated for 60 s. All the patients undergoing the procedure were preloaded with P_2Y_{12} inhibitor and were on aspirin before coronary angioplasty. Unfractionated heparin was given as per the standard hospital practice and the activated clotting time was maintained above 250 s. The procedure was performed via radial access according to the usual hospital practice.

All the patients were investigated for any adverse cardiac events that occurred during the hospital stay or during follow-up period. The adverse events include cardiac death, any myocardial infarction, symptom driven target vessel revascularization or target lesion revascularization (TLR). Target lesion revascularization (TLR) was defined as any patient presenting with acute coronary syndrome (ACS) or chest pain during follow-up, with angiographic evidence of >50 % in-stent or peri-stent restenosis requiring reintervention. Cardiac death was defined as death due to heart failure during follow-up or any sudden cardiac death of presumed cardiac origin.

2.3. Study devices

The MagicTouch is a sirolimus-coated balloon represents an innovative approach to balloon technology, featuring a sirolimus coating applied uniformly through spray coating techniques at a dosage of 1.27 μg/mm^2. Additionally, its Nanolute technology introduces a breakthrough solution to sirolimus's low lipophilicity by enveloping it within a protective lipophilic package which facilitates drug diffusion, penetration, and sustained residency within the arterial wall post-balloon inflation. Sirolimus is circumferentially distributed around the balloon's surface and within its folds, with about 66 % remaining within these folds and only 34 % exposed to blood prior to deployment. This strategic distribution minimizes drug loss during transit.

The Agent balloon catheter consists of a semi-compliant paclitaxel balloon coated with a blend of paclitaxel (low dose formulation, 2 μg/mm^2) and inactive excipient acetyl-tri-n-butyl citrate.

2.4. Statistical analysis

Statistical analysis was conducted using R software version 4.3.3 (The R Foundation, Vienna, Austria). Continuous variables were expressed as mean ± standard deviation and compared using Student's *t*-test, while categorical variables were presented as numbers and percentages and compared using the Chi-square test or Fisher exact test, as appropriate. Primary endpoints were estimated using Kaplan–Meier survival analysis, and group comparisons were made using the log-rank test. A multivariable Cox proportional hazards regression analysis was conducted to address potential confounding factors. The proportional hazards assumption was tested and found to be valid for all variables, with a global Schoenfeld residuals *p*-value of 0.72, ensuring the reliability of the Cox regression model. All reported *p*-values were two-sided, with values less than 0.05 considered statistically significant.

3. Results

Eighty-five patients with DES-ISR were enrolled in this study, among them 32 were assigned to the PCB group and 53 to the SCB group.

Table 1
Clinical baseline characteristics.

Characteristics	Total ($n = 85$)	Paclitaxel DCB ($n = 32$)	Sirolimus DCB ($n = 53$)	*p*-value
Age (years, mean ± SD)	65.80 ± 8.48	63.50 ± 8.54	67.19 ± 8.21	0.051
Male, n (%)	77 (90.6 %)	31 (96.9 %)	46 (86.8 %)	0.151
Diabetes mellitus, n (%)	65 (76.5 %)	26 (81.3 %)	39 (73.6 %)	0.420
Hypertension, n (%)	65 (76.5 %)	27 (84.4 %)	38 (71.7 %)	0.182
Chronic kidney disease, n (%)	14 (16.5 %)	5 (15.6 %)	9 (17.0 %)	0.870
No. of lesion*	**n = 91**	**n = 34**	**n = 57**	–
LAD, n (%)	35 (38.5 %)	15 (44.1 %)	20 (35.1 %)	0.537
LCx, n (%)	22 (24.2 %)	9 (26.5 %)	13 (22.8 %)	
LM, n (%)	4 (4.4 %)	0 (0 %)	4 (7 %)	
RCA, n (%)	28 (30.7 %)	9 (26.5 %)	19 (33.3 %)	
SVG, n (%)	2 (2.2 %)	1 (2.9 %)	1 (1.8 %)	

Continuous variables were compared using Student's *t*-test, and categorical variables were compared using the Chi-square test or Fisher exact test, as appropriate. $p < 0.05$ was considered statistically significant. *A total of 91 lesions were treated with DCB in 85 patients suggesting multiple lesions (≥2) in few patients.

DCB: Drug-coated balloon; LAD: Left anterior descending artery; LCX: Left circumflex artery; LM: Left main artery; RCA: Right coronary artery; SVG: Saphenous vein graft.

Baseline and lesion characteristics of the patients are demonstrated in Table 1. Overall, 90.6 % of the study population were men. The mean age of the patients in PCB group was 63.50 ± 8.54 years and of SCB group was 67.19 ± 8.21 years. The proportion of the patients with diabetes and hypertension was observed to be higher in PCB group when compared to SCB group (81.3 % vs 73.6 % and 84.4 % vs 71.7 %, respectively). However, only 15.6 % patients in PCB and 17 % patients in SCB group were diagnosed to have chronic kidney disease. A total of 57 lesions were treated with SCB while 34 lesions were treated with PCB.

Table 2 displays the procedural details of the enrolled patients, in which a total of 97 DCB were used to treat 85 patients with DES-ISR. The average length of PCB was 24.11 ± 6.54 mm and SCB was 29.58 ± 7.98 mm. The mean diameter of the PCB was 3.20 ± 0.43 mm and SCB was 3.31 ± 0.39 mm. The IVUS imagining was used to measure pre- and post-dilatation MSA. A significant difference was noted in the post-dilatation MSA observed among PCB group was 7.01 ± 1.11 mm^2 and among SCB group it was 8.0 ± 1.70 mm^2 ($p = 0.005$).

Clinical events during the follow-up were noted in both the groups (Table 3). At mean follow-up of 3.8 years, no cardiac death was observed in PCB group and one (8.3 %) cardiac death was observed in SCB group; however, the difference was not statistically significant ($p = 0.459$). The TLR was observed in one (12.5 %) patient among the PCB group and in four (16.5 %) patients in SCB group ($p = 0.920$). Fig. 1 indicates the cumulative event-free survival probability of patients in both the groups.

After adjusting the key covariates, the hazard ratio (HR) for the PCB group compared to the SCB group was 0.752 (95 % CI: 0.078–7.281, $p = 0.806$), indicating no statistically significant difference between the two groups. Furthermore, age did not have a significant impact on survival ($p = 0.424$). Although diabetes mellitus (DM) showed a trend toward increased hazard (HR = 1.906, 95 % CI: 0.202–17.998, $p = 0.574$), but lacks statistical significance. Other comorbidities such as hypertension ($p = 0.712$) and chronic kidney disease ($p = 0.823$) did not significantly impact outcomes. These findings suggest that, after adjusting for baseline characteristics, there was no significant difference between the two treatment groups in terms of the primary endpoint (Table 4).

4. Discussion

The DCBs have emerged as a vital therapeutic modality, in the management of small vessel coronary artery disease and in-stent restenosis.[12,13] The first clinical indication for DCBs was ISR, with studies showing safety and feasibility, as well as better outcomes compared to plain old balloon angioplasty (POBA) and comparable results to DES.[12] DCB presents advantages over DES such as shortened DAPT duration and prompt, uniform drug release, resulting in reduced inflammatory responses within vessels.[13] The concept behind DCB involves delivering an anti-proliferative drug to the vessel wall while inflating the balloon, without leaving any permanent implant. In this study we have compared the safety and efficacy of two widely used anti-proliferative DCBs, i.e., PCB and SCB in patients with DES-ISR. A recent study, compared DCB alone with newer-generation DES in patients with STEMI due to ISR and found no difference in fractional flow reserve at nine months, suggesting that DCBs could be a viable alternative in patient with ISR.[12] Another study by Giacoppo D and his colleagues[14] exhibited that a composite of all-cause death, myocardial infarction, and target lesion thrombosis tended to occur more frequently in DES-ISR treated with another DES than with DCB. One advantage of DCB angioplasty is that it avoids leaving metallic struts within treated vessels. Although thrombotic complications can stem from various factors, it is apparent that the slow healing of metallic struts in implanted DES, along with their tendency to provoke chronic inflammation, significantly increases the risk of stent thrombosis.

In the present study, mean age the patients among both the groups was comparable to the age of the population enrolled in earlier study.[11]

Table 2
Procedural details.

Characteristics	Total ($n = 85$)	Paclitaxel DCB ($n = 32$)	Sirolimus DCB ($n = 53$)	p-value
Drug-coated balloon* (n)	97	37	60	–
Pre-dilatation IVUS measured MSA, mm^2	2.66 ± 0.86	2.41 ± 0.93	2.81 ± 0.77	0.025
Post-dilatation IVUS measured MSA, mm^2	7.65 ± 1.57	7.01 ± 1.11	8.0 ± 1.70	0.005
DCB length mm	27.49 ± 7.90	24.11 ± 6.54	29.58 ± 7.98	0.001
DCB diameter, mm	3.27 ± 0.41	3.20 ± 0.43	3.31 ± 0.39	0.158

Data are represented as frequency or mean ± standard deviation. Continuous variables were compared using Student's t-test, and categorical variables were compared using the Chi-square test or Fisher exact test, as appropriate. $p < 0.05$ was considered statistically significant. *A total of 91 lesions were treated in 85 patients with 97 DCB which suggests use of multiple DCB in few patients.
DCB: Drug-coated balloon; IVUS: Intravascular ultrasound; MSA: Minimal stent area.

Table 3
Clinical outcomes at follow-up of 3.8 median years.

Outcomes	Total ($n = 85$)	Paclitaxel DCB ($n = 32$)	Sirolimus DCB ($n = 53$)	p-value
Cardiac death, n (%)	1	0 (0 %)	1 (8.3 %)	0.459
TLR, n (%)	5	1 (12.5 %)	4 (16.5 %)	0.920

Endpoints were estimated using Kaplan–Meier survival analysis, and group comparisons were made using the log-rank test. $p < 0.05$ was considered statistically significant.
DCB: Drug-coated balloon; TLR: Target lesion revascularization.

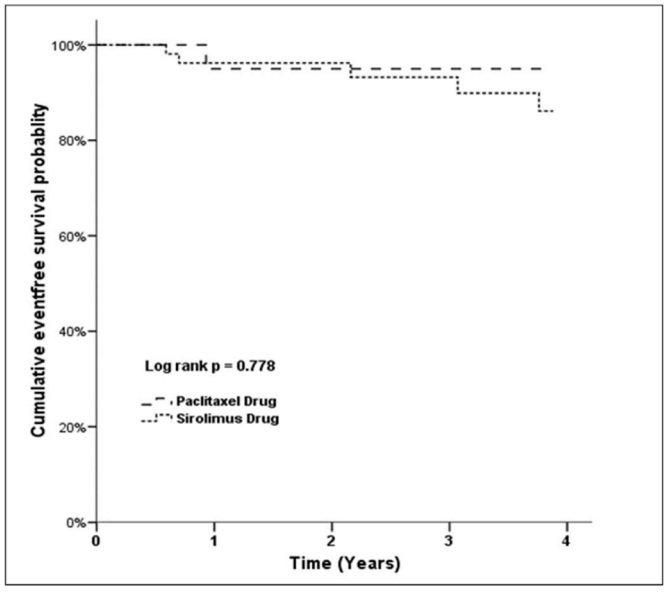

Fig. 1. Kaplan Meier curve: cumulative event free survival probability.

Table 4
Multivariable analysis results.

	Hazard Ratio (HR)	95 % CI (HR)	p-value
Paclitaxel vs. Sirolimus	0.752	0.078–7.281	0.806
Age	1.038	0.947–1.137	0.424
Diabetes Mellitus	1.906	0.202–17.998	0.574
Hypertension	1.526	0.162–14.373	0.712
Chronic kidney disease	0.776	0.084–7.147	0.823

A study conducted by Wilson S et al,[1] found that patients with certain underlying diseases, such as diabetes and chronic kidney disease, are at significantly higher risk of developing ISR. Furthermore, a review article highlighted that besides patient-related and stent design factors, the characteristics of the treated lesion also play a crucial role in development of ISR.[15]

The diameter of the PCB balloon used in our study was 3.20 ± 0.43 mm and SCB was 3.31 ± 0.39 mm. However, in a randomized controlled trial, the diameters of the PCB and SCB balloons were observed to be slightly smaller than in our study (2.92 ± 0.39 mm vs 2.90 ± 0.41 mm).[11] The previously conducted studies used quantitative coronary angiography (QCA) and the late lumen loss to observe the procedural success.[11] However, in our study, the procedure was guided using IVUS technique in treating ISR. IVUS offers distinct advantages over angiography such as it exhibits more sensitivity in detecting ISR, especially in cases of diffuse ISR or ISR in small vessels. IVUS also facilitates the identification of the underlying mechanism and substrate of ISR, provides guidance for lesion preparation, and confirms a satisfactory result post-intervention.[16] Additionally, IVUS provides detailed cross-sectional images of the coronary artery, enabling precise measurement of the lumen area, stent area, and plaque burden.[4,16]

The SIRPAC study by Cortese B et al,[17] compared 290 patients each in the PCB and SCB groups who underwent treatment for ISR. At 12 months clinical follow-up, no difference in TLR rates (8.3 % vs 7.9 %, respectively; $p = 0.879$), and MACE rate (10.7 % vs 10.3 %, respectively; $p = 0.892$) was observed between the PCB and SCB groups. In our study, at 3.8 median years of follow-up, no cardiac death was reported PCB group and one (8.3 %) in SCB group; however, the difference was not statistically significant ($p = 0.459$). Similarly, TLR was 12.5 % in PCB group and 16.5 % in SCB group but was not statistically significant ($p = 0.920$). Furthermore, the cumulative event-free survival in both groups did not show statistical significance ($p = 0.778$) in the present study (Fig. 1). In contrast, the ISAR DESIRE 3 trail reported a lower MACE rate in the PCB group compared to the SCB group at one year follow-up (22 % vs 31.5 %, $p = 0.03$).[18] The difference in the incidence of MACE between the PCB and SCB groups could be attributed to the mode of action of both drugs. Paclitaxel is the preferred drug for coating due to its irreversible binding to the microtubes resulting in prolonged persistence in vascular cells and favourable cell-specific effects. In contrast, sirolimus and its analogues bind reversibly, requiring longer contact and release time for effective inhibition of neointimal proliferation.[11] These differences in mode of action between both drugs may contribute to the variations in MACE rates. However, factors such as type of coating over balloon, balloon material and the actual contact time also effect the incidences of MACE.

5. Limitations

Some potential limitations should be considered. Since it was a hospital-based study conducted at a tertiary care hospital and including a small sample size, generalizability of the findings may be limited. Furthermore, the chosen target lesions were DES-related ISR; hence, the findings may not be transferred to other scenarios. A formal power calculation was not performed for this pilot study, which may limit the statistical power to detect differences in TLR or MACE, though multivariable analysis was used to adjust for baseline imbalances. However, based on current findings, we are going to design a larger multi-centre study on all type of ISR using drug-eluting balloons with longer follow-up and using QCA and imaging modalities.

6. Conclusion

In conclusion, both PCB and SCB could be used in treatment of DES-ISR. No statistical difference in the incidence of adverse events, including cardiac death and TLR, were observed among patients treated with PCB or SCB was noted. This suggests that both paclitaxel and sirolimus eluting coronary balloons may confer similar clinical advantage in terms of safety and effectiveness in patients with DES-related ISR; however, this needs to be validated in larger study on heterogenous population.

Impact on daily practice

- The results of the present suggest use of drug-coated balloons (DCBs), such as paclitaxel-coated balloons (PCBs) and sirolimus-coated balloons (SCBs), as effective and safe treatment option for managing in-stent restenosis (ISR) following drug-eluting stent implantation, with no significant differences observed in adverse events like cardiac death and target lesion revascularization rates between the two types of DCBs.
- The findings of this study support the use of DCBs as a viable alternative to drug-eluting stents for the treatment of ISR, potentially avoiding the need for repeated stenting and reducing the risks associated with long-term dual antiplatelet therapy, while still providing effective revascularization.
- The use of intravascular imaging techniques, particularly intravascular ultrasound (IVUS), plays a crucial role in optimizing treatment outcomes by enabling proper lesion assessment, guiding lesion preparation, and confirming satisfactory results post-intervention.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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